

Review Date: _____

Additional DHHS protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Checklist for Protocol # _____

The purpose of this checklist is to aid you in your evaluation of CDC research involving prisoners inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. These requirements are in addition to those imposed under other subparts of the Federal Regulation.

Minimal Risk

The Federal Regulations divide research into that which is minimal or not greater than minimal risk to the participant and that which is greater than minimal risk. The definition of minimal risk for research involving prisoners is given in §46.303(d), which reads as follows:

“Minimal risk is the **probability** and **magnitude** of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of health persons.”

Level of Risk for this protocol (please insert “minimal” or “greater than minimal”):

An IRB can only approve research that falls into one of the following four categories (complete/check one only):

45 CFR 46 Subpart “C” § 46.306		
Category		Notes
<i>Cause and Effect</i>	“study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided...	
	...that the study presents no more than minimal risk AND	
	no more than inconvenience to the subjects.”	
<i>Institutional Structures</i>	“study of prisons as institutional structures or of prisoners as incarcerated persons, provided ...	
	...that the study presents no more than minimal risk AND	
	no more than inconvenience to the subjects.”	

45 CFR 46 Subpart "C"		
§ 46.306		
Category		Notes
<i>Conditions Affecting Prisoners as Class</i>	"research on conditions particularly affecting prisoners as a class (e.g., vaccine trials ...on hepatitis which is much more prevalent in prisons; and research on social and psychological problems such as alcoholism, drug addition, and sexual assaults)..."	
<i>Improving Health and Well-being</i>	"research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject."	

Please use the following determination key when evaluating research involving prisoners to ensure that the **additional safeguard** has been satisfactorily addressed:

- Y** = adequately addressed in protocol
M = missing in protocol
I = incomplete or problematic in protocol

Additional Safeguard		§ 46.305	Notes
<i>Legal</i>		“research...limited by applicable State or local law.”	
<i>Controls</i>		“Unless the PI provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed...”	
<i>Advantages</i>		“any possible advantages accruing to the prisoner through his or her participation..., when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks...against the value of such advantages in the limited choice environment of the prison is impaired;	
<i>Risks</i>		...are commensurate with risks that would be accepted by nonprisoner volunteers;	
<i>Selection</i>		“procedures...are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.	
<i>Comprehension</i>		“...information is presented in language which is understandable...”	
<i>Parole</i>		“adequate assurance exists that parole boards will not take into account a prisoner’s participation...in making decisions regarding parole, and each prisoner is clearly informed in advance that participation...will have no effect on his or her parole...”	
<i>Follow-up</i>		“where the Board finds there may be a need for follow-up examination or care...after...participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.”	